DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 16 2007

Re: GEM 21S Growth-Factor Enhanced Matrix
Docket No.: 2006E-0234

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,124,316, filed by Biomimetic Therapeutics, Inc. (previously Biomimetic Pharmaceuticals,Inc.), under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for GEM 21S Growth-Factor Enhanced Matrix, the medical device claimed by the patent.

The total length of the regulatory review period for GEM 21S Growth-Factor Enhanced Matrix is 1,361 days. Of this time, 744 days occurred during the testing phase and 617 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: February 28, 2002.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on February 28, 2002.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: March 12, 2004.

   FDA has verified the applicant's claim that the premarket approval application (PMA) for GEM 21S Growth-Factor Enhanced Matrix (PMA P040013) was initially submitted on March 12, 2004.

3. The date the application was approved: November 18, 2005.

   FDA has verified the applicant's claim that PMA P040013 was approved on November 18, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Paul T. Clark
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